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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,146	10/02/2001	Eric G. Lovett	279.262US1	9587
21186	7590	10/05/2005		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			EXAMINER SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tate

Office Action Summary	Application No.	Applicant(s)	
	09/970,146	LOVETT ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 0719.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 58-69 is/are pending in the application.
4a) Of the above claim(s) 2, 11, 15, 17-20, 24, 25, 27, 30-32 and 34-37 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 02 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I (claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29 and 33) in the reply filed on July 19, 2005 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3 and 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (Pat. No. 6,514,237).

Regarding claim 1, the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode with the electroactive polymer representing the rheometric material electrically coupled to the electrode. Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature.

Regarding claim 3, note col. 6, lines 4-7.

Regarding claim 4, the assembly of Maseda comprises a rheometric material layer between platinum anode/cathode electrodes. The outer surface of the electrode can arbitrarily be assigned as the side upon which the rheometric layer resides on top of.

Regarding claims 5 and 6 and claims with similar limitations, one can arbitrarily designate one side of the catheter body to constitute a first surface with the opposite side of the body constituting a second surface. Since the rheometric material can be attached to the body such as set forth in col. 5, lines 56-67, one strand or electrode

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(note the rejection of claim 1) can be placed in a groove on one side of the catheter, while another strand or electrode is placed in a groove on the opposite side.

Regarding claim 7, the applicant is not claiming a pulse generator, but merely a lead body configured to be coupled to a pulse generator. The fact that the electroactive material at the distal end of the device body must be connected to a power supply at the proximal end as per col. 5, lines 40-55 dictates that the lead body be configured to be coupled to a pulse generator.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lieber et al. (Pat. No. 4,329,993) in view of Maseda

Lieber et al. disclose a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teaches that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous from the standpoint of increasing flexibility and steerability of the catheter as it is introduced into the body. Increased maneuverability through the tortuous vasculature system, high precision, and ease of placement –very important design considerations for the medical artisan-- make the incorporation of the Maseda assembly and related control system on the medical device of Lieber et al. an obvious choice. Related comments apply to claims 23 and 28.

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Regarding claims 10, 26 and 60, see col. 5, lines 40-55 and col. 8, lines 33-36 of Maseda.

Regarding claims 12-14, 58 and 59, Maseda discloses that the assembly material may be disposed about the device body in a variety of arrangements including wrapping the material about the outer surface of the body, and using a plurality of assemblies.

Regarding claim 16, it is axiomatic that one desiring to control the insertion of a medical device would want to control the distal tip to prevent tissue damage and permit maximum maneuverability. To place the assembly about the distal tip would have been considered blatantly obvious.

Regarding claims 22 and 33, one can consider port 36 to be a preformed curved length portion.

Regarding claims 61 and 62, note col. 6, lines 7-12 of Maseda.

Regarding claims 63 and 67, the assembly of Maseda comprises a rheometric material layer between platinum anode/cathode electrodes. The outer surface of the electrode can arbitrarily be assigned as the side upon which the rheometric layer resides on top of.

Regarding claim 65, comments related to those made above in the rejection of claim 9 apply here as well, wherein the second electrode is considered to be one of the platinum electrodes of the Maseda assembly (see the rejection of claim 1 above).

Regarding claim 66, both electrodes must inherently be electrically coupled if they are to function as electrodes (i.e., they must be either coupled to a source of energy in order to activate the rheometric assembly or stimulate the electrode 35).

Response to Arguments

6. Applicants' arguments filed February 28, 2005 have been fully considered but they are not persuasive.

Regarding the rejection of claim 1, applicants state that they cannot find at least one electrode coupled with the device body that is configured to transmit and receive electrical signals to and from tissue. Applicants further argue that the conductive

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platinum electrode of Maseda is not shown as being configured to transmit and receive electrical signals to and from tissue. The examiner cannot find in the claim where it is stated that the electrode must perform transmission and reception of electrical signals to and from tissue. The examiner cannot find any structure in the claim for generating such signals and sensing such signals. The electrode only need be *capable* of such action. Platinum electrodes are inherently capable of transmitting and receiving electrical signals to and from the body due to their conductive and biocompatible nature. The applicants state in their own specification that platinum can be used as an electrode to conduct electricity (page 14, lines 14-24). The platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive bodily fluids. The platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from the tissue.

The applicants' amendments and the concomitant new grounds of rejection have rendered the rest of the applicants' arguments moot.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rebell (Pat. No. 4,917,104) shows substantially similar lead structure to that of Bakels et al. wherein a cap electrode 22 is disposed at the distal end. Shahinpoor et al. disclose the use of biomimetic sensors and actuators with Pt dendritic type electrodes.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on M-F at 571 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
October 1, 2005



KENNEDY SCHAETZLE
PRIMARY EXAMINER